



# UNITED STATES PATENT AND TRADEMARK OFFICE

ET

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,332	06/27/2001	Joseph Solus	0942.4250003	4572
26111	7590	05/31/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/891,332

Applicant(s)

SOLUS ET AL.

Examiner

Joyce Tung

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 August 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,5-11,13-15,17-28,31-33,66 and 69-82 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1,2,5-11,13-15,17-28,31-33,66 and 69-82 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 8/31/2005.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

The applicant's request for continued examination filed 8/31/2005 has been entered.

Claims 1-2, 5-11, 13-15, 17-28, 31-33, 66, and 69-82 are pending.

#### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114.

Applicant's submission filed on 8/31/2005 has been entered.

#### *Claim Rejections - 35 USC § 102*

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1-2, 5-11, 13-15, 17-20, 23-28, 31-33, 66 and 69-82 are rejected under 35 U.S.C. 102(e) as being anticipated by Hughes et al. (5939301, issued August 17, 1999).

Hughes et al. disclose a method of DNA sequencing with thermostable mutant polymerases (See the Abstract, column 20, lines 24-47). The mutant polymerase can be used in molecular biology (See column 3, lines 18-20) such as sequencing and amplification (See column 1, 39-41). The mutant polymerase is the mutant of *Thermotoga neapolitana* (Tne)

Art Unit: 1637

polymerase (See the abstract). The mutant polymerase has reduced 3' to 5' exonuclease activity, 5'-3' exonuclease activity and mutation in the O-helix of the polymerase (See the abstract, column 1, lines 29-41, column 7, lines 6-15, column 8, lines 41-67). The DNA polymerase mutant ~~has~~ substitutes a Tyr for Phe at amino acid position 67 and other changes within the O-helix (See column 9, lines 6-13). Hughes et al. also disclose a kit containing the mutant polymerase Tne (See column 12, lines 5-34).

Hughes et al. do not explicitly disclose that the mutant polymerase reduces the ability to add one or more non-templated nucleotides to the 3' terminus of a synthesized DNA molecule and produces a population of amplified DNA fragments, wherein less than about 50% of the amplified DNA fragments have one or more non-templated 3' nucleotide compared to amplification products produced by *Taq* DNA polymerase assayed under the same condition as recited in claims 1, 2, 23 and 66. However, these limitations set forth above are the results of the method or the function of the mutant polymerase. Since the mutant polymerase of Hughes et al. has the same mutated position as the mutated polymerase recited in the instant claims, it is inherent that both mutated polymerases ~~are having~~<sup>are</sup> the same function. In addition as both mutated polymerases are applied in the same amplification conditions, it would have the same results as recited in the claims.

Moreover, the limitations discussed above are recited as function limitations and results of the method. These limitations do not have patentable weight.

Claims 69-82 further recite the limitations regarding the results of the method or the function of the mutated polymerase. As discussed above, these limitations do not have patentable weight. Thus, the teachings of Hughes anticipate the limitations of the claims.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hughes et al. (5939301, issued August 17, 1999) as applied to claims 1-2, 5-11, 13-15, 17-20, 23-28, 31-33, and 66-82 above, and further in view of Huo (5,922,535, issued July 13, 1999).

The teachings of Hughes et al. are set forth in section 3 above. Hughes et al. do not disclose determining the relationship between a first individual and a second individual in which the first individual is known and the second individual is unknown via polymerase chain reaction

Huo discloses the method for the detection of sequence differences between nucleic acid populations (See column 3, lines 65-67). Huo indicated that in the conventional way, the normal

Art Unit: 1637

sequence is already known as compared with the sequence associated with a disorder (See column 1, lines 13-20).

One of ordinary skill in the art at time of the invention would have been motivated to modify the amplification method of Hughes et al. by involving a known sequence population as taught by Huo to determine the relationship between two individual populations via polymerase chain reaction. The motivation is that the method of Huo provides<sup>a</sup> tool that can be used to identify polymorphisms in genomic DNA, to identify genetic mutations associated with disease states (See column 1, lines 54-58). Thus, it would have<sup>been</sup> prima facie obvious to carry out the method to determine the relationships between two individuals by using known individual via polymerase chain reaction.

### Summary

6. No claims are allowable.
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J. Tung*  
May 24, 2006

*Kenneth R. Horlick*  
KENNETH R. HORLICK, PH.D  
PRIMARY EXAMINER  
5/25/06